IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF SOUTH CAROLINA
ROCK HILL DIVISION

United States of America, *ex rel.* [FILED UNDER SEAL],	Civ. A. No. 0:18-02341-JMC
Plaintiffs-Relators,	AMENDED COMPLAINT (Jury Trial Demanded)
v.	(Anti-Kickback, 42 U.S.C. §§ 1320a-7b(b)) (False Claims Act, 31 U.S.C. §§ 3729-3733)
[FILED UNDER SEAL],	
Defendant.	**DO NOT PLACE IN PRESS BOX** **DO NOT ENTER ON PACER**

FILED *IN CAMERA* AND UNDER SEAL
PURSUANT TO 31 U.S.C. § 3730(b)(2)

This *qui tam* action is brought by [FILED UNDER SEAL], an individual, on behalf of the United States of America ("United States" or "Government"), against [FILED UNDER SEAL] for treble damages and civil penalties arising from [FILED UNDER SEAL] unlawful scheme to defraud the United States' Medicare, Medicaid, and TRICARE programs ("Payors") by knowingly causing the submission of false or fraudulent claims for reimbursement in violation of the False Claims Act, as amended, 31 U.S.C. §§ 3729 *et seq.* (the "FCA"), and by entering into an unlawful referral and kickback scheme in violation of the Anti-Kickback Statute, 42 U.S.C. §§ 1320a-7b(b) (the "AKS").

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF SOUTH CAROLINA
ROCK HILL DIVISION

United States of America, *ex rel.* Christopher Paul Grant and Tymekah Danielle Ferguson, Plaintiffs-Relators, v. Health Screening Services, LLC, Nick Turner, Integrated Care, LLC, Sasha Cahill and LabSolutions, LLC, Minal Patel, CLIO Laboratories, LLC and Yousef Ismail Emtairah, Defendants.	)	Civ. A. No. 0:18-02341-JMC AMENDED COMPLAINT (Jury Trial Demanded) (Anti-Kickback, 42 U.S.C. §§ 1320a-7b(b)) (False Claims Act, 31 U.S.C. §§ 3729-3733) **DO NOT PLACE IN PRESS BOX** **DO NOT ENTER ON PACER**

FILED *IN CAMERA* AND UNDER SEAL
PURSUANT TO 31 U.S.C. § 3730(b)(2)

This *qui tam* action is brought by Plaintiffs-Relators Christopher Paul Grant and Tymekah Danielle Ferguson ("Relators", "Grant" or "Ferguson") on behalf of the United States of America ("United States" or "Government"), against Defendants Health Screening Services, LLC ("HSS"), Integrated Care, LLC ("Integrated"), Nick Turner ("Turner"), Sasha Cahill ("Cahill"), LabSolutions, LLC (LabSolutions"), Minal Patel ("Patel"), CLIO Laboratories, LLC ("CLIO") and Yousef Ismail Emtairah ("Emtairah") for treble damages and civil penalties arising from Defendants' unlawful scheme to defraud the United States' Medicare, Medicaid, and TRICARE programs ("Payors") by knowingly causing the submission of false or fraudulent claims for reimbursement in violation of the False Claims Act, as amended, 31 U.S.C. §§ 3729 *et*

seq. (the "FCA"), and by entering into an unlawful referral and kickback scheme in violation of the Anti-Kickback Statute, 42 U.S.C. §§ 1320a-7b(b) (the "AKS").

JURISDICTION AND VENUE

1. This action arises under the laws of the United States of America to redress violations of the AKS and FCA. The Court has subject-matter jurisdiction over this *qui tam* action pursuant to 28 U.S.C. §§ 1331 and 1345, and 31 U.S.C. §§ 3732(a) and 3730(b). Relators are not aware of any other complaints filed against Defendants that make the same or similar allegations, or of any public disclosure of the allegations and information contained in the Complaint and Amended Complaint. Therefore, Relators are the original source of all information upon which the Complaint and Amended Complaint are based as defined by the FCA and as described more fully herein. Relators have direct and independent knowledge of the information on which the allegations herein are based and voluntarily provided this information to the federal government.

2. This Court has personal jurisdiction over Defendants because Defendants do business in the United States, including in South Carolina. Specifically, personal jurisdiction is proper because (1) nationwide service of process is authorized by 31 U.S.C. § 3732(a), and (2). Defendants have sufficient minimum contacts with the United States as a whole, and South Carolina in particular, including that Defendants can be found in this State, transact or have transacted business in this State, contract to supply services or things in this State, and enter into contracts to be performed in whole or in part in this State.

3. This Court is a proper venue for this *qui tam* action under 28 U.S.C. § 1391(b) and 31 U.S.C. § 3732(a), because a substantial part of the events or omissions giving rise to these

claims occurred here and because Defendants regularly transact business in the District of South Carolina.

4. As required by the FCA, Relators are providing the Attorney General of the United States and the United States Attorney for the District of South Carolina with a statement of all material evidence and information related to this Amended Complaint. This disclosure statement is supported by material evidence known to Relators at the time of the filing of this Amended Complaint that establishes that Defendants deliberately submitted false claims to the Government, caused the deliberate submission of false claims by Defendants to the Government, and entered into an illegal referral arrangement in violation of the AKS.

***IN CAMERA* REVIEW**

5. Pursuant to 31 U.S.C. § 3730(b)(2), this Amended Complaint is to be filed *in camera* and is to remain under seal for a period of at least 60 days and shall not be served on Defendants until this Court so orders.

THE PARTIES

Plaintiff-Relator Christopher P. Grant

6. Plaintiff-Relator Christopher P. Grant is a citizen of the United States of America and the State of South Carolina. Grant is suing Defendants, in the name of, and on behalf of, the United States of America. Grant brings this action based upon his direct, independent, and personal knowledge of the facts alleged herein, and also on his information and belief.

7. In July 2018, Grant in his employment as a sales representative for Alliance Family of Companies, Inc. ("Alliance"), met Sasha Cahill, owner and CEO of Integrated.

8. As part of this introduction, Cahill informed Grant that she would like to send him referrals for routine and video EEG tests as part of his employment with Alliance.

9. During their discussions, Cahill informed Grant of her scheme to provide free medical assistants to physicians so she could receive referrals for pharmacogenetic, cancer and other laboratory testing. Cahill also informed Grant that she was providing computer software to physicians at below fair market value to obtain referrals.

10. Grant has had numerous meetings with Cahill and she has openly asked him to provide her leads to hospitals and health care systems and other physicians so that she can utilize her scheme to obtain additional referrals for laboratory testing.

11. Grant has received information regarding Integrated's business operations from (1) Cahill; (2) the medical assistants Cahill and Integrated employ; (3) Patrick Stella ("Stella"), Operations Manager for Integrated and HSS; (4) Anna Saleh ("Saleh"); and, (5) John Lewallen ("Lewallen") regarding Integrated's business operations. Grant has received Integrated materials directly from Cahill's employees regarding how Integrated obtains referrals from physicians, how the scheme is perpetrated and how the testing is submitted to Defendant LabSolutions and CLIO for reimbursement from the Government programs.

12. Cahill has also provided Grant with detailed information regarding HSS and HSS's owner and CEO Nick Turner, and how Integrated and HSS work together and how their business models and schemes are related.

13. Stella works for both Integrated and HSS as their Operations Manager and he has provided detailed information to Grant regarding how HSS and Integrated's models and schemes work and how they fraudulently obtain referrals from physicians. Stella has also provided information to Grant as to how Integrated and HSS obtain the greatest reimbursement from the Government for the testing referrals.

14. Upon information and belief, Cahill and Stella are utilizing this fraudulent scheme at the Palmetto Medical Group in Indian Land, South Carolina. Upon information and belief, Integrated and HSS have worked out a compensation agreement for all referrals that are received from Palmetto Medical Group. Cahill and Stella have informed Grant that Integrated and HSS have used this fraudulent scheme in physician offices which are located in South Carolina, Georgia, North Carolina, Texas and California.

15. Grant has also spoken with Lewallen and other Integrated and HSS medical assistants who have provided information regarding Integrated's relationship with Defendant LabSolutions and how tests are referred to Defendant LabSolutions by Integrated.

16. Grant has gained an intimate knowledge of the schemes of HSS and Integrated, the utilization of medical assistants to obtain referrals and the providing of computer software to physicians at below fair market value. Grant has also been provided with information regarding Defendants LabSolutions and CLIO's direct involvement in the fraudulent scheme and reimbursement to Integrated and HSS for the referrals. Grant has obtained this direct knowledge from Cahill, Stella, Lewallen, Saleh and the medical assistants regarding how the fraudulent scheme has been implemented to obtain referrals and how the Defendants are attempting to obtain a greater volume of referrals from physicians through this fraudulent scheme.

Plaintiff-Relator Tymekah Danielle Ferguson

17. Plaintiff-Relator Tymekah Danielle Ferguson is a citizen of the United States of America and the State of North Carolina. Ferguson is suing Defendants, in the name of, and on behalf of, the United States of America. Ferguson brings this action based upon her direct, independent, and personal knowledge of the facts alleged herein, and also on her information and belief.

18. Ferguson was employed by Integrated and worked as a medical assistant on behalf of Integrated. She was involved in the daily activities of Integrated and the processing of laboratory testing with LabSolutions and other work performed for Integrated. She has integral knowledge of the work performed by the medical assistants for physician practices that are outside the scope of employment with Integrated and the elaborate fraudulent scheme that Integrated has implemented. Ferguson had daily conversations with Cahill, Stella and Saleh regarding Integrated operations, how to obtain additional referrals from physicians, and how to insure that testing was not rejected by Medicare or Medicaid.

Defendants Health Screening Services, LLC and Nick Turner

19. Defendant Health Screening Services, LLC, was founded on or around 2014 and is a health management services company headquartered in Dallas, Texas. Defendant HSS provides health management services to help physicians identify and screen patients for genetic, cancer, blood, neurological, sleep and other testing throughout the United States. HSS's current owner and CEO is Nick Turner.

Defendant Integrated Care, LLC and Sasha Cahill

20. Defendant Integrated Care, LLC, was founded on or around 2014 and is a health management services company headquartered in Charlotte, North Carolina. Defendant Integrated provides health management services to help physicians identify and screen patients for genetic, cancer, blood, neurological, sleep and other testing throughout the United States. Integrated's current owner and CEO is Sasha Cahill.

Defendants LabSolutions, LLC and Minal Patel

21. Defendant LabSolutions, LLC , was founded on or around 2013 and is a privately held laboratory testing company headquartered in Atlanta, Georgia. Minal Patel is the owner and

CEO of Defendant LabSolutions. Defendant provides molecular, clinical chemistry and toxicology laboratory testing throughout the United States.

Defendants CLIO Laboratories, LLC and Yousef Ismail Emtairah

22. Defendant CLIO Laboratories, LLC, was founded on or around 2015 and is a privately held laboratory testing company headquartered in Atlanta, Georgia. Yousef Ismail Emtairah is the owner Defendant CLIO. Defendant provides pharmacogenetics testing and toxicology laboratory testing throughout the United States.

FACTUAL BACKGROUND

I. INTRODUCTION

This case involves a fraud against the Medicare, Medicaid and TRICARE programs though an illegal kickback scheme used to induce Medicare, Medicaid and TRICARE providers to request pharmacogenetic testing, hereditary cancer screening, inherited disease carrier screening, hematology and toxicology screening, and allergy and sleep apnea testing.

Upon information and belief, Nick Turner, Owner and CEO of HSS, and Sasha Cahill, Owner and CEO of Integrated discovered a lucrative scheme to defraud Medicare, Medicaid and TRICARE by providing free medical assistants **at no charge to the physicians**. The free medical assistants are employed by Integrated and HSS and perform any and all tasks that they are asked to perform by the physician practices including but not limited to screening patients, conducting wellness visits and medical assessments, ordering allergy and EEG tests, filling out paperwork, completing electronic medical records, uploading documents to the physicians EMR database, taking the weight, height and other measurements for patients, performing EKGs, taking vital signs, buying flowers, and picking up lunch. The medical assistants also utilize the

computers, printers and fax machines of the physician offices if they needed to perform clerical tasks.

Defendants Integrated and HSS have also provided physicians with ThoughtSwift software at a reduced fee which is below fair market value. This software allows physicians to conduct Electronic Health Assessments ("EHAs") and to bill Medicare, Medicaid and TRICARE for the EHAs which are performed by Integrated medical assistants. The ThoughtSwift software also allows the physicians the ability to generate more revenue because they can obtain more reimbursement for referrals that are made from information obtained through the utilization of software. Integrated and HSS are providing this software in an effort to generate more testing referrals from the physicians and keeping the physicians happy by helping them generate more revenue.

This scheme could not work without the assistance of a laboratory to conduct the testing and to bill Medicare, Medicaid and TRICARE for reimbursement. Defendants HSS, Integrated, Turner and Cahill have conspired, and continue to conspire, with LabSolutions, Patel, CLIO and Emtairah to implement this fraudulent scheme. This fraudulent scheme targets Medicare, Medicaid and TRICARE doctors and patients and LabSolutions and CLIO bill Medicare, Medicaid and TRICARE for reimbursement for the fraudulent referrals. In particular, the Defendants know, that unlike many private insurance payers, Medicare pays for 100% of the cost of pharmacogenomic test panels, so Defendants hone in on physicians with a high-percentage of Medicare, Medicaid and TRICARE patients.

As part of this scheme, Defendants HSS, Integrated, Turner and Cahill have the medical assistants working in the physician's offices order medically unnecessary tests that are not required and which have not been reviewed by the physicians. Integrated and HSS through

Stella and Saleh have instructed medical assistants to order laboratory tests even if the medical necessity criteria have not been satisfied. The medical assistants make these referrals for medically unnecessary tests that physicians have not reviewed to allow for Integrated and HSS to receive additional reimbursement from Medicare, Medicaid and TRICARE. This scheme generates greater revenue for Defendants. The medical assistants have also been instructed on how to insure that Medicare will not reject CGX and PGX testing that is performed on the same day.

HSS, Integrated, Turner and Cahill have worked out lucrative contracts with LabSolutions, Patel, CLIO and Emtairah to conduct the testing that is required. LabSolutions and CLIO will reimburse Turner and Cahill and their companies for the fraudulent claims that are submitted to Medicare, Medicaid and TRICARE for reimbursement.

II. DEFENDANTS' FRAUDULENT SCHEME TO REQUEST LABORATORY TESTING FOR UNLAWFUL KICKBACKS.

A. Pharmacogenomic, Genetic, Cancer, Hereditary and Inherited Disease testing is an area ripe for fraud.

1. Pharmacogenomics is a relatively new but exploding area of research that studies how genetic variations influence individual's response to drugs. Pharmacogenomics uses a saliva-based testing method to detect genetic enzymes associated with the metabolism medications, thereby measuring whether and individual properly metabolizes certain drugs.

2. As part of this process, additional hereditary testing can be done for cancer screening or other inherited diseases which patients could carry based upon their familial history. The genetic carrier testing uses the latest genetic sequencing technology to screen for and possibly prevent over sixty serious inherited diseases just like doctors treat with other diseases.

3. Nick Turner, Sasha Cahill and their companies have marketed themselves as leading ancillary companies offering clinical continuum of care with a focus on maximizing quality outcomes while lowering the overall cost of treatment. These companies have stated that they understand the business of medicine and are established to serve physicians and their practices by providing the resources that they need to walk patients through the medical journey.

4. Cahill and Integrated have stated on their website that their company "provides pharmacogenetic testing, hereditary cancer testing, inherited disease carrier testing, EHAs, annual wellness visits, sleep apnea testing, EEGs, allergy testing, pharmacy and dispensary assistance and nerve conduction studies." Integrated and HSS do not perform any of the testing that they say they can perform and they are third party companies who funnel the testing and other procedures to laboratories and other companies.

5. Integrated and HSS also have focused their scheme on how to increase physician profits, particularly for those physicians that have a large number of Medicare patients. For example, Integrated's website states that "our goal is to find and implement ancillary services that generate high ROI for your practice and draw better outcomes for your patients." The website further states that "the average practice that works with us, generates around $5,000-$9,000 per month in ancillary revenue with no contract or investment needed from the clinic."

6. Patrick Stella has stated that HSS and Integrated concentrate on States that have high Medicare reimbursement rates which will allow these companies to have greater reimbursement for the referrals that they receive. Cahill has repeatedly stated that she wants to increase her volume as much as possible through this scheme and be able to attain health systems instead of physician offices. She has stated that she would like to be like Walmart as opposed to Whole Foods in the volume of referrals that she obtains for laboratory testing.

B. Defendants' fraudulent scheme of providing free medical assistants to physicians to obtain referrals

7. Turner, Cahill and their companies have implemented a fraudulent scheme which focuses on providing free medical assistants to physicians in order to receive referrals for laboratory testing.

8. As part of their scheme, Defendants know that physicians are not appropriately staffed to handle the everyday ins and outs of testing, paperwork and other administrative tasks associated with their patients. They also know that the small physician practices do not have the revenue to justify a full time employee who is in charge of administering tests, completing paperwork and handling other related items related to testing.

9. In order to prey on the physicians, Defendants have implemented a scheme to provide free medical assistants to the physicians to help them in completing the tests and paperwork for pharmocogenetic, cancer, hereditary, allergy and other testing. The scheme allows Integrated and HSS to have medical assistants on the inside who can obtain and direct referrals for testing while at the same time providing a free benefit to physicians.

10. Defendants not only provide the free medical assistants to help with the testing and patient screening but the free medical assistants also provide work outside of what is required for Integrated and HSS. The work outside the scope of their employment with Integrated and HSS includes EHAs designed to meet the preventative care standards of current federal mandates, inputing electronic medical records, uploading documents into the physician's EMR database, performing EKGs, taking vital signs for patients and performing height, weight and other patient medical checks, ordering flowers and picking up lunch. The medical assistants also handle referrals for allergy, sleep, EEGs and video EEGs and items not related to Integrated and HSS testing. The medical assistants are also involved in the screening and evaluation of

patients and Cahill has indicated that medical assistants have handled the physical reviews of patients on behalf of physicians. The medical assistants also utilize the computers, printers and fax machines of the physician offices if they need to perform clerical tasks.

11. The medical assistants are paid by Integrated and HSS and the physicians do not pay Integrated or HSS for the utilization of the medical assistants. Furthermore, the physicians are not in control of the medical assistants and if there are issues with the medical assistants then Integrated or HSS are asked to handle the issues.

12. The scheme set up by Integrated and HSS is based upon the greater the volume of referrals the greater the reimbursement. Upon information and belief, Cahill directs the medical assistants to produce a high volume of referrals by selecting patients each day which can generate referrals for testing.

13. The medical assistants review patient lists of the physicians at the beginning of the day and are trained on the best way to insure that the patients fall within the criteria needed to obtain referrals for testing. Once the patients arrive, the medical assistants meet with the patients and ask them a series of questions that have been drafted by Integrated and HSS. Upon information and belief, the questions asked by the medical assistants are formulated to insure that the patients will need referrals for testing.

14. Cahill has told medical assistants to make sure that they tell patients that they are part of the physician's office and that they work for the physicians and are there to provide preventative care to the patients. After the medical assistants finish the questioning of the patient, the medical assistants have been told by Cahill to tell the patients that the testing is 100% covered by Medicare or Medicaid and that they will not receive a bill. Upon information and belief, Cahill and Integrated have told the medical assistants to inform the patients that the

testing is covered by Medicare so that the patients will consent to the test. After the medical assistants receive patient consent, the patient is asked for a sample of saliva for the tests.

15. At the end of the day, the medical assistants will arrange all the samples which they have selected for testing and the physicians will then sign the order forms requesting testing services. The medical assistants are trained on how to insure that they receive the appropriate approval from the physicians for testing referrals. Upon information and belief, the physicians rely solely on the medical assistants to tell them which samples need to be sent for testing based upon the information that was received by the medical assistants during the questioning of the patients. Upon information and belief, a significant amount of tests submitted by the medical assistants are not medically necessary and should not have been signed off by the physician or sent out for testing.

16. Upon information and belief, Stella and Saleh, on behalf of Integrated and HSS, have instructed medical assistants to obtain at least 15 referrals per medical assistant for testing per day. Stella and Saleh have instructed medical assistants to increase their referrals for laboratory testing and have trained medical assistants on how to increase referrals even though the referrals may not be medically necessary. Stella and Saleh, on behalf of Integrated and HSS, have instructed medical assistants to only handle testing referrals which are related to Medicare, Medicaid and TRICARE and to not spend time on private insurance tests. Cahill has stated that she wants the medical assistants "hopping" and doing more in the practices to obtain referrals.

17. Integrated and HSS utilize the services of Patrick Stella, Operations Manager, to insure that the medical assistants are creating as many referrals as possible from the physician practices. In essence, Stella has been designated to monitor the medical assistants and make sure they are steadily making referrals for laboratory testing. Stella goes into the physician practices

to review paperwork, supervise and shadow the medical assistants and evaluate the number of referrals made.

18. Upon information and belief, Defendants have contractual agreements with Defendants LabSolutions and CLIO for referrals made by the medical assistants located at the physician practices. Integrated and HSS have directed the medical assistants to send the testing referrals to Defendants LabSolutions and CLIO. Defendants receive a set reimbursement from LabSolutions and CLIO for each referral made to LabSolutions and CLIO. Upon information and belief, LabSolutions and CLIO are directly involved in the scheme and have full knowledge of the means that are utilized by Integrated and HSS to obtain the fraudulent referrals that are sent to LabSolutions and CLIO.

19. Upon information and belief, the medical assistants have been placed into the physician practices in order to direct the referrals to Defendants LabSolutions and CLIO because of the monetary arrangement that exists between all of the Defendants for payment.

C. Defendant Integrated and HSS's fraudulent scheme to provide below fair market value computer software to physicians

20. In conjunction with providing free medical assistants, Defendants Integrated and HSS have provided physicians with ThoughtSwift EHA software. This software allows the physicians to complete assessments of patients to meet the preventative care standards of current federal mandates.

21. Integrated and HSS are allowing the physicians to utilize this software for a small fee that is below fair market value. Cahill has stated that the only reason that the physicians are even having to pay a small fee is to avoid it being seen as a **kickback**.

22. Upon information and belief, the medical assistants perform the EHAs utilizing the ThoughtSwift EHA software for patients who come to the physician practices. The EHAs

are then sent to Integrated and HSS directly by email. Upon information and belief, Integrated and HSS then notifies the physician practices of the EHAs that have been performed each day and the physician practices will bill Medicare directly for these items even though the physician and his staff did not personally perform the EHAs.

23. The utilization of the software by the physician allows Integrated and HSS to provide the physicians a way to generate additional revenue for the physicians because they can bill Medicare for the EHAs and they can send more patients out for tests and procedures (ie EEGs and sleep apnea) for which they are receiving reimbursement from Medicare and Medicaid. The providing of the software is a kickback which allows the physicians to be able to obtain additional revenue for their practices.

24. Integrated and HSS have trained the medical assistants on how to increase the ancillary revenue obtained by the physician practices through additional tests and patient procedures obtained through the use of the software.

D. Defendants Integrated and HSS arrangements with Defendant LabSolutions, Patel, CLIO and Emtairah for reimbursement for illegal and fraudulent referrals

25. Upon information and belief, Defendants HSS, Integrated, Turner and Cahill have agreements with Defendants LabSolutions and CLIO to conduct genetic, hereditary, allergy, blood and additional testing that is referred from the physician practices where Defendants Integrated and HSS have provided physicians with kickbacks.

26. Upon information and belief, LabSolutions, Patel, CLIO and Emtairah have full knowledge of the fraudulent scheme that is in place and they are aware of the manner in which fraudulent referrals are obtained by Integrated and HSS and sent to LabSolutions and CLIO.

27. Upon information and belief, Defendants HSS, Integrated, Turner and Cahill have an agreement with Defendants LabSolutions and CLIO whereby they are reimbursed for all referrals that are made to LabSolutions and CLIO by the physician practices who have contracted with Integrated and HSS.

28. Integrated, HSS, Cahill and Turner have worked out an arrangement between themselves as to how they will split the reimbursements received from Defendants LabSolutions and CLIO for any referrals that are made from the physician practices to LabSolutions and CLIO. They have agreements in place governing the revenue sharing between all of the companies. The greater the reimbursement by Defendants LabSolutions and CLIO means the greater reimbursement for Integrated and HSS.

E. Defendants Procure Medically Unnecessary Tests from Physicians

29. Integrated and HSS medical assistants are trained to instruct physicians on how to obtain reimbursement for procedures and which procedures can obtain the largest reimbursement. In particular, Stella has stated that Integrated and HSS look for physician practices in states that provide greater reimbursement for the laboratory tests so that Integrated and HSS can obtain greater reimbursement from Defendants LabSolutions and CLIO.

30. Integrated and HSS medical assistants use the ThoughtSwift software to perform medical assessments on patients. After utilizing the software, medical assistants are instructed to obtain as many referrals for testing as they can even if they are not medically necessary. The medical assistants see the patients before the physicians and determine which patients need testing without any input from the physicians. The medical assistants will tell the physicians at the end of the day which patients need referrals for testing. The physicians sign the referral forms without reviewing the information or determining if the tests are medically necessary. The

physicians rely solely on the medical assistants to determine if testing is medically necessary. Upon information and belief, Integrated and HSS medical assistants refer medically unnecessary tests for testing at the direction of Integrated and HSS.

31. As part of this arrangement, medical assistants perform CGX (Cancer Genomic Screening) and PGX (Pharmacogenetic) testing on the same date at the physician's offices but are told by Integrated, Cahill, Stella and Saleh to not send the tests to the laboratory on the same date because Medicare will not reimburse for these tests if they are done on the same date. To accomplish this fraudulent scheme, Integrated, Cahill, Stella and Saleh have told medical assistants to incorrectly label the dates that the testing was done on the forms sent to the laboratory so that reimbursement can be accomplished. The physicians and their practices sign off on these tests even though the incorrect dates are listed on the lab referral forms.

32. The medical assistants are trained by Stella and Saleh on how to refer medically unnecessary tests to Defendants LabSolutions and CLIO. The medical assistants are instructed on how to list fraudulent criteria on the order forms to provide coverage if Medicare Medicaid or TRICARE requests additional information. One example involves where patients do not fit within the appropriate medical criteria but Stella and Saleh tell medical assistants to list that the patient has a mood disorder which requires further testing simply because the patient is taking several medications. Stella and Saleh have trained the medical assistants on ways to fraudulent submit tests which are not medically necessary.

33. Stella and Saleh shadow medical assistants to determine if they are obtaining the most referrals as possible. Stella and Saleh have told medical assistants that the more referrals they send means more money for Integrated and HSS. Stella and Saleh have ordered medical assistants to obtain referrals for at least 15 tests per day.

34. Integrated and HSS medical assistants are told by Stella, Saleh, Cahill and Turner to obtain greater referrals for laboratory tests which will increase the reimbursements from Medicare. They are told to specifically concentrate on Medicare and Medicaid patients and to not spend time on private insurance patients. Stella has stated that placement of the medical assistants in the practices allows the medical assistants to ask questions and obtain information which leads to greater referrals and that putting the medical assistants in the physician offices holds everything together for Integrated and HSS.

35. Upon information and belief, the medical assistants are also trained about using a policy to promulgate more referrals by using a lower standard for medical necessity than that approved by the Medicare program.

MEDICARE, MEDICAID, TRICARE, AND LABORATORY TESTING

The Medicare Program

1. The Health Insurance for the Aged and Disabled Act (Title XVIII of the Social Security Act), 42 U.S.C. §§ 1395 *et seq.*, commonly known as Medicare, is a health insurance program designed to assist the nation's elderly meet their healthcare costs. Medicare also provides coverage for younger individuals who are permanently disabled.

2. Among other benefits, Medicare includes hospital insurance under Part A and supplemental medical insurance ("SMI") under Part B. Medicare Part B, 42 U.S.C. §§ 1395c-1395w-6, is a voluntary medical insurance plan designed to supplement hospital insurance coverage. Part B is financed by premiums paid monthly by enrollees which are subsidized by the Government.

3. Generally, Medicare Part B provides coverage for items or services that: (1) fall within a defined Medicare benefit category; (2) are not excluded from coverage by statute,

regulation, National Coverage Determination ("NCD"), or Local Coverage Determination ("LCD"); and (3) are determined to be reasonable and necessary for the treatment of an illness or injury.

4. Specifically, Medicare Part B provides coverage for "medical and other health services." 42 U.S.C. § 1395l(a)(1). Section 1395x(s)(3) defines "medical and other health services" to include "diagnostic tests." Section 1395y(a)(1)(A), however, excludes from coverage any item or service which is not "reasonable and necessary for the diagnosis or treatment of illness or injury."

5. Pharmocogenic and other genetic tests that are paid for by Medicare on the Medicare Physician Fee Schedule ("MPFS"). *See generally* 42 C.F.R. § 410.32(b)

6. The service providers (*e.g.*, LabSolutions and CLIO) submit claims for payment of testing to the Government health programs directly, including Medicare.

The Medicaid Program

7. Medicaid is a joint federal-state program that provides healthcare benefits for certain groups; primarily the poor and disabled. Each state administers its own Medicaid program, under federal regulations that generally govern what services should be provided and under what conditions. CMS monitors the state-run programs and establishes requirements for service delivery, quality, funding, and eligibility standards.

8. The Government provides a portion of each state's Medicaid funding. The portion provided is known as the Federal Medical Assistance Percentage ("FMAP") and is based on the state's per capita income compared to the national average. 42 U.S.C. § 1396d(b).

9. Like Medicare, a "claim" under Medicaid is only reimbursable if it is "reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member". 42 C.F.R. § 402.3.

The TRICARE Program

10. In 1967, the Department of Defense created the Civilian Health and Medical Program of the Uniformed Services ("CHAMPUS"), which is a federally funded medical program created by Congress. 10 U.S.C. § 1071. CHAMPUS beneficiaries include active military personnel, retired personnel, and dependents of both active and retired personnel. *Id*.

11. In 1995, the Department of Defense established TRICARE, a managed healthcare program, which operates as a supplement to CHAMPUS. *See* 32 C.F.R. §§ 199.4, 199.17(a). Since the establishment of TRICARE in 1995, both programs are frequently referred to collectively as TRICARE/CHAMPUS, or just "TRICARE." The purpose of the TRICARE program is to improve healthcare services to beneficiaries by creating "managed care support contracts that include special arrangements with civilian sector health care providers." 32 C.F.R. § 199.17(a)(1). The TRICARE Management Activity ("TMA") oversees this program.

12. The TRICARE managed healthcare programs are created through contracts with managed care contractors in three geographic regions: North, South, and West. TRICARE health services are provided through both network, and non-network, participating providers. Providers who are Medicare-certified providers are also considered TRICARE-authorized providers. TRICARE-authorized providers are either "Network Providers" or "Non-Network Providers."

13. "Network Providers" include hospitals, other authorized medical facilities, doctors and healthcare professionals, all of whom enter into an agreement with the region's managed care contractor, and provide services for an agreed reimbursement rate. 32 C.F.R. §

199.14(a). "Non-Network Participating Providers" include hospitals, other authorized medical facilities, doctors and healthcare professionals who do not enter an agreement with the region's managed care provider, and are reimbursed at rates established by TRICARE regulations. *Id*.

14. Just as with Medicare and Medicaid, TRICARE providers have an obligation to provide services and supplies at only the appropriate level and "only when and to the extent medically necessary." 32 C.F.R. § 199.6(a)(5).

15. TRICARE's governing regulations, like Medicare's and Medicaid's requirements also are based upon "medical necessity." TRICARE's governing regulations require that services provided be "furnished at the appropriate level and only when and to the extent medically necessary," and such care must "meet professionally recognized standards of health care [and be] supported by adequate medical documentation . . . to evidence the medical necessity and quality of services furnished, as well as the appropriateness of the level of care." 32 C.F.R. 199.6(a)(5). In this respect, similar to Medicare and Medicaid, services provided at a level higher than the medically necessary are improper and violations of TRICARE. *Id*.

THE ANTI-KICKBACK STATUTE AND FALSE CLAIMS ACT

16. The Anti-Kickback Statute prohibits the knowing and willful payment of "remuneration" to induce or reward patient referrals or the generation of business involving any item or service payable by the Federal healthcare programs. A violation of the AKS also constitutes a violation of the False Claims Act, which provides, in relevant part:

> any person who (A) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval; (B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim; (C) conspires to commit a violation of subparagraph (A), (B), (C) . . . or (G); . . . or (G) knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government,

> is liable to the United States Government for a civil penalty of not less than [$10,957] and not more than [$21,916] . . . plus 3 times the amount of damages which the Government sustains because of the act of that person.
>
> * * *
>
> (b) For purposes of this section, the terms the terms "knowing" and "knowingly" (A) mean that a person, with respect to information (i) has actual knowledge of the information; (ii) acts in deliberate ignorance of the truth or falsity of the information; or (iii) acts in reckless disregard of the truth or falsity of the information; and (B) require no proof of specific intent to defraud[.]

See 42 U.S.C. § 1320a-7b(b), 31 U.S.C. § 3729(a)-(b) (civil penalties adjusted by the DOJ effective Feb. 3, 2017 pursuant to the Federal Civil Penalties Inflation Adjustment Act of 1990, *see* 28 C.F.R. § 85.5 (2017)).

COUNT 1 (VIOLATION OF FALSE CLAIMS ACT, 31 U.S.C. §3729(A)(1)(A))

17. Relators incorporate herein by reference the preceding paragraphs of this Amended Complaint as though fully set forth herein.

18. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented or caused to be presented, and upon information and belief, are still presenting or causing to be presented, to the United States of America false or fraudulent claims for payment or approval, in violation of 31 U.S.C. § 3729 (a)(1)(A).

19. In particular, Defendants knowingly presented or caused to be presented, and upon information and belief, are continuing to present or causing to be presented, to the United States of America false or fraudulent claims for payment or approval based on conduct in violation of the Anti-kickback Statute and/or the Stark Law. Defendants caused and are continuing to cause physicians and other medical professionals to order pharmacogenomic genetic tests and other tests reimbursed by Medicare by provided kickbacks and illegal

inducements to the physicians and medical professionals. Defendants provided and are continuing to provide the kickbacks and illegal inducements in the form of free medical assistants and computer software at below fair market value, in violation of 31 U.S.C. § 3729 (a)(1)(A).

20. Defendants also knowingly presented or caused to be presented, and upon information and belief, are continuing to present or causing to be presented, to the United States of America false or fraudulent claims for payment or approval of pharmacogenetic, cancer and other tests that were not medically necessary. Tests were not medically necessary because Defendants are continuing to have medical assistants have physicians request unnecessary tests, regardless of the physician's consideration of individual medical necessity, in violation of 31 U.S.C. § 3729 (a)(1)(A). Also, tests were not medically necessary because Defendants were inducing physicians and other medical professionals to apply a lower standard for medical necessity than that required by the Medicare program, in violation of 31 U.S.C. § 3729 (a)(1)(A).

21. Defendants also knowingly presented or caused to be presented, and upon information and belief, are continuing to present or causing to be presented, to the United States of America false or fraudulent claims for payment or approval of pharmocogenetic, cancer and other tests based on Defendants LabSolutions and CLIO's false certification of compliance with laws and regulations. On information and belief, as an Independent Diagnostic Testing Facility ("IDTF") enrolled to provide services reimbursed by Medicare, LabSolutions and CLIO are required to fill out a certificate of compliance with the Anti-kickback Statute, the Stark Law, the False Claims Act, state false claims acts and similar statutes, and/or other law and regulations, LabSolutions certificates of compliance become and continue to be false or fraudulent, in violation of 31 U.S.C. § 3729 (a)(1)(A).

22. As a result of the conduct set forth in this cause of action, the Government suffers and continues to suffer harm as a result of paying or reimbursing for tests which, had the Government known such tests were being ordered as a result of the conduct, the Government would not otherwise have paid for/or reimbursed.

23. By reason of the Defendants' acts in violation of the False Claims Act, the United States has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

COUNT 2 (VIOLATION OF FALSE CLAIMS ACT, 31 U.S.C. §3729(A)(1)(B))

24. Relators incorporate herein by reference the preceding paragraphs of this Amended Complaint as though fully set forth herein.

25. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and upon information and belief, are still making, using or causing to be made or used, a false record or statement marital to a false or fraudulent claim, in violation of 31 U.S.C. § 3729 (a)(1)(B).

26. In particular, Defendants knowingly made, used, or caused to be made or used, and upon information and belief, are still making, using, or causing to be made or used, false or fraudulent claims for payment or approval based on conduct in violation of the Anti-kickback Statute and/or the Stark Law. Defendants caused and are continuing to cause physicians and other medical professionals to order pharmacogenetic, cancer and other tests reimbursed by Medicare by providing kickbacks and illegal inducements to the physicians and medical professionals. Defendants provided and are continuing to provide the kickbacks and illegal

inducements in the form of free medical assistants and computer software at below market value, in violation of 31 U.S.C. § 3729 (a)(1)(B).

27. Defendants also knowingly made, used, or caused to be made or used, and upon information and belief, are still making, using, or causing to be made or used, false or fraudulent claims for payment or approval of pharmocogenetic, cancer and tests based on Defendants LabSolutions and CLIO's false certification of compliance with laws and regulations. On information and belief, as an Independent Diagnostic Testing Facility ("IDTF") enrolled to provide services reimbursed by Medicare, LabSolutions and CLIO are required to fill out a certificate of compliance with the Anti-Kickback Statute, the Stark Law, and other laws and regulations. By committing acts in violation of the Anti-kickback Statute, the Stark Law, the False Claims Act, state false claims acts or similar statutes, and/or other laws and regulations, the LabSolutions and CLIO certificates of compliance became and continue to be false and fraudulent, 31 U.S.C. § 3729 (a)(1)(B).

28. As a result of the conduct set forth in this cause of action, the Government suffers and continues to suffer harm as a result of paying or reimbursing for tests which, had the Government known such tests were being ordered as a result of the conduct, the Government would not otherwise have paid for/or reimbursed.

29. By reason of the Defendants' acts in violation of the False Claims Act, the United States has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

COUNT 3 (VIOLATION OF FALSE CLAIMS ACT, 31 U.S.C. §3729(A)(1)(C))

30. Relators incorporate herein by reference the preceding paragraphs of this Amended Complaint as though fully set forth herein.

31. As detailed above, Defendants knowingly conspired, and upon information and belief, continue to conspire with each other and with health care professionals and medical assistants and other intermediaries, to commit acts in violation of 31 U.S.C. § 3729 (a)(1)(A) and (B). Defendants and these health care professionals and medical assistants committed overt acts in furtherance of the conspiracy as described above.

32. As a result of the conduct set forth in this cause of action, the Government suffers and continues to suffer harm as a result of paying or reimbursing for tests which, had the government known such tests were being ordered as a result of the conduct, the Government would not otherwise have paid for/or reimbursed.

33. By reason of the Defendants' acts in violation of the False Claim Act, the United States has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

PRAYER FOR RELIEF

Wherefore, Relators respectfully request this Court to enter judgment against Defendants, as follows:

a. That the Defendants be ordered to cease and desist from submitting or causing to be submitted any more false or fraudulent claims, or making, using, or causing to be made or used, false records or statements material to a false or fraudulent claim or further violating 31 U.S.C. § 3729 *et seq.*, the Anti-kickback Statute, and/or the Stark Law;

b. That judgment be entered in Relators' favor and against Defendants in the amount of each and every false or fraudulent claim, plus three times the amount of damages as provided for in 31 U.S.C. § 3729(a), plus a civil penalty of not less than five thousand five hundred ($5,500) or more than eleven thousand dollars ($11,000) per claim as

provided by U.S.C. § 3729(a), to the extent such multiplied penalties shall fairly compensate the United States of America for losses resulting from the various schemed undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

c. That Relators be awarded the maximum amount allowed pursuant to U.S.C. § 3730(d), including reasonable attorneys' fees and litigation costs;

d. That judgment be granted for Relators and against Defendants for all costs, including but not limited to court costs, expert fees and all attorneys' fees incurred by Relators in the prosecution of this suit; and

e. That Relators be granted such other and further relief as the Court deems just and proper.

DEMAND FOR JURY TRIAL

Relators, on behalf of himself and the United States, demands a jury trial on all issues so triable.

Respectfully Submitted,

Dated: August 30, 2018

/s/ R. Mills Ariail, Jr.
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